JUL 2 3 2002

K012974

510(k) SUMMARY of SAFETY and EFFECTIVENESS

I. GENERAL INFORMATION

Trade or (Proprietary) Name: Prizm Medical, Inc. ThermoTrace™ Infrared Thermometer Models 15004 and 15007

Common or usual name: Thermometer, electronic, clinical

Classification Name: FDA has classified thermometer, electronic, clinical as Class II devices. (21 C.F.R. § 880.2910)

Submitter's Name And Address:
Cathryn N. Cambria
for Prizm Medical, Inc.
Regulatory Resources Group
5536 Trowbridge Drive
Dunwoody, GA 30338

Submission Date: September 4, 2001

Legally Marketed Device To Which Claim Substantial Equivalence:
J & J Engineering, Inc. Thermistor Thermometer
Exergen Corporation DermaTemp DT 1001

II. INDICATIONS FOR USE

The Prizm Medical, Inc. ThermoTrace™ Infrared Thermometer Models 15004 and 15007 are intended for use in clinical settings for the intermittent measurement and monitoring of surface skin temperature on people of all ages.

III. DEVICE DESCRIPTION

The Prizm Medical, Inc. ThermoTrace™ Infrared Thermometer Models 15004 and 15007 are a hand held instrument that measures skin temperature based on measuring infrared radiation. It is designed for ease of patient use with clearly marked patient intensity buttons. The indications for use are to measure and monitor the patient's skin temperature. It is intended for use on people of all ages.

Please refer to the Operations Manual (Exhibit A) for photographs and a more thorough description of the device.

The Prizm Medical, Inc. ThermoTrace™ Infrared Thermometer Models 15004 and 15007 are intended for use in clinical settings for the intermittent measurement and monitoring of surface skin temperature on people of all ages. The primary function of

the ThermoTrace™ Infrared Thermometer Models 15004 and 15007 are the same as the J & J Engineering, Inc. Thermistor Thermometer and the Exergen Corporation DermaTemp DT 1001 and raises no new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Prizm Medical, Incorporated
C/O Ms. Cathryn N. Cambria
Regulatory Resources Group, Incorporated
5536 Trowbridge Drive
Dunwoody, Georgia 30338

Re: K012974
Trade/Device Name: Prizm Medical Inc. Thermotrace™ Infrared Thermometer, Models 15004 and 15007
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: July 3, 2002
Received: July 10, 2002

Dear Ms. Cambria:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 2

Prizm Medical, Inc.

510(k) Number (if known): K012974

Device Name: Prizm Medical, Inc. ThermoTrace™ Infrared Thermometer Models 15004 and 15007

Indications for Use:

The Prizm Medical, Inc. ThermoTrace™ Infrared Thermometer Models 15004 and 15007 are a hand held instrument intended for use in clinical settings for the intermittent measurement and monitoring of skin temperature variations [redacted] wmB

wmB [redacted] on people of all ages.

(PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR Over-The-Counter Use ____ wmB
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012974